

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

In items 4 and 6 on page 1 of the Office Action, claims 1-6, 8, 9 and 11-23 are incorrectly listed as pending and rejected. Kindly note that claim 2 was previously cancelled and claims 14-23 were withdrawn from consideration as non-elected subject matter. Thus, claims 1, 3-6, 8, 9 and 11-23 are pending, and claims 1, 3-6, 8, 9 and 11-13 are rejected.

Claim 1 is amended to replace “pre-balanced with a culture medium” with “adhered to a support and rinsed with a culture medium and further comprises the culture medium.” Support for this amendment can be found at page 25, lines 6-8 and page 27, lines 15-15, wherein a rinsing step with a culture medium is disclosed. It is respectfully submitted that this rinsing step is sufficient to constitute “pre-balanced with a culture medium.” After the rinsing step, the culture medium remains in the tissue section. As a result, the rinsed tissue section is easy to handle for cell culture.

Claim 11 is amended to depend on claim 1, and not on claim 10, which was previously cancelled.

New claims 24 and 25 have been added. Support for claims 24-25 can be found at page 5, lines 16-22, page 10, line 19 to page 11, line 12 (Figs. 11-14), page 24, lines 1-8 and Examples 3-5 on pages 27-32.

Therefore, no new matter has been added by this amendment.

Claims 1, 3-6, 8, 9 and 11-25 are pending upon entry of this amendment.

## **II. INDEFINITESS REJECTION**

On pages 2-3 of the Office Action, claims 1, 3-6, 8, 9 and 11-13 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the phrase “pre-balanced with a culture medium.”

This rejection is respectfully traversed as applied to the amended and new claims.

As noted above, claim 1 is amended to replace “pre-balanced with a culture medium” with “rinsed with a culture medium and further comprises the culture medium.” Again, support can be found at page 25, lines 6-8 and page 27, lines 15-16. At this location, the specification clearly discloses a rinsing step with a culture medium to “pre-balance” the tissue section with a culture medium. It is respectfully submitted that the culture medium remains in the tissue section after rinsing, and thus, the rinsed tissue section is easy handle for cell culture.

In view of the above, the rejection of claims 1, 3-6, 8, 9 and 11-13 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

## **III. ANTICIPATION REJECTION**

On pages 3-4 of the Office Action, claims 1, 3-6, 8, 9 and 11-13 were rejected under 35 U.S.C. § 102(b) as anticipated by Ried, U.S. 5,919,624.

This rejection is respectfully traversed as applied to the amended and new claims.

To anticipate a claim, a cited prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131.01.

Claim 1 is amended to specify that the tissue section is “rinsed with a culture medium and further comprises the culture medium.” The limitation “rinsed with a culture medium” is sufficient to “pre-balance” the tissue section with a culture medium. After rinsing, the culture medium remains in the tissue section. Consequently, the rinsed tissue section is easy to handle for cell culture.

The cited patent fails to disclose a tissue section which had been rinsed with a culture medium and which further comprises the culture medium. Instead, it is respectfully submitted that all of the tissue sections described in the Ried patent are not in contact with a culture medium. Consequently, the tissue section in Ried does not further comprise the culture medium, and thus, the tissue sections in Reid do not have the property of being easy to handle for cell culture. Consequently, the Ried patent fails to disclose each and every element in the claimed invention.

In view of the above, the rejection of claims 1, 3-6, 8, 9 and 11-13 under 35 U.S.C. § 102(b) is untenable and should be withdrawn.

#### **IV. OBVIOUSNESS REJECTION**

On pages 4-8 of the Office Action, claims 1, 3-6, 8, 9 and 11-13 were rejected under 35 U.S.C. § 103(a) as obvious over Badylak et al, WO 99/12555 and Mori et al., Anat. Embryol., Vol. 199, pp. 319-327, 1999, taken with Ried et al., U.S. 5,919,624 and Sitte, U.S. 3,785,234.

This rejection is respectfully traversed as applied to the amended and new claims.

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. See M.P.E.P. § 2143.01. Second, there must be some suggestion or motivation in the references to either modify or combined the referenced teachings to arrive at the claimed invention. See M.P.E.P. § 2143.01. Third, the prior art must provide a reasonable expectation of success. See M.P.E.P. § 2143.02.

Again, claim 1 is amended to specify that the tissue section is “rinsed with a culture medium and further comprises the culture medium.”

It is respectfully submitted that the cited prior art references fail to disclose each and every element of the claimed invention, in particular, the rinsing step with a culture medium and a tissue section further comprising a culture medium. Also, it is respectfully submitted that the combined teachings of the cited references would not motivate one of ordinary skill in the art to

prepare an animal-derived or plant-derived tissue section-containing carrier according to the claimed invention.

WO 99/12555 is generally directed to the use of submucosal tissue which is enzymatically treated with galactosidase which can be implanted to replace or support damaged or diseased tissues or to form a cell culture growth substrate. The submucosal tissue has a thickness of about 100 to 200  $\mu\text{m}$  and consists primarily of acellular, extracellular matrix material. See the Abstract and page 4, lines 30-32.

There is no suggestion in the reference that other tissue sections from animals or plants may be used as a cell culture growth substrate, nor that the cell culture substrate may have a thickness of from 0.5 to 50  $\mu\text{m}$ . There is also no suggestion of a rinsing step with a culture medium, such that a culture medium remains in the tissue section.

Mori also fails to disclose or suggest the use of an animal-derived or plant-derived tissue section in a thickness of 0.5 to 50  $\mu\text{m}$  used as a substrate for seeding and culturing animal cells. Instead, Mori describes cutting neonatal mouse liver tissues into 250  $\mu\text{m}$  slices and culturing the tissue to maintain the parenchymal cells and ontogenesis and to investigate their proliferation and differentiation. There is no teaching or suggestion of using the tissue section as a cell culture substrate.

The Ried patent is directed to methods of detecting the presence of cervical carcinoma by examining tissue sections. There is no teaching or suggestion of using the tissue section as a cell culture growth substrate.

The Sitte patent is directed to devices for cutting thin tissue sections.

No where in the combined teachings of the cited references is there a suggestion for a tissue section-containing carrier derived from animal or plant, for seeding and culturing animal cells, wherein the tissue section having thickness of 0.5 to 50  $\mu\text{m}$  is adhered to a support and rinsed with a culture medium and further comprises the culture medium. Furthermore, the

Attorney Docket No. 2001\_1784A  
Serial No. 09/980,246  
December 8, 2005

present invention does not require the numerous other treatment steps for the tissue section in the prior art.

In view of the above, the rejection of claims 1, 3-6, 8, 9 and 11-13 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Toshiaki TAKEZAWA et al.

By:

  
\_\_\_\_\_  
Jay F. Williams

Registration No. 48,036

for

Warren M. Cheek, Jr.  
Registration No. 33,367  
Attorneys for Applicants

WMC/JFW/akl  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
December 8, 2005